UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**
THIS DOCUMENT RELATES TO: *Wave 4 Cases*	

EXPERT REPORT OF MICHAEL M. FIEGEN, M.D.

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Report regarding the TVT and TVT-O mid-urethral slings

This report contains my opinions about the efficacy and safety of the Ethicon TVT and TVT-O devices, the appropriateness of the devices' labeling, and the bases for my opinions. My opinions are based on my training, education, and experience in the field of urogynecology, on the documents and materials discussed and/or cited in this report, and on the documents and materials included on the attached list of materials reviewed. I am being compensated $458 per hour for my work on this matter. I hold the opinions in this report to a reasonable degree of medical and scientific certainty, and reserve the right to supplement or amend my opinions, if necessary, if I receive additional information.

I have not testified as an expert witness in the preceding four years.

I. Background

My educational background includes graduation from O'Gorman High School in Sioux Falls, SD in 1970. I entered the US Navy during the Vietnam conflict and was a part of the Defense Intelligence Department until my Honorable Discharge in 1974. I enrolled in college at the University of South Dakota in 1974 and competed a degree in Chemistry in 1978. I entered Medical School at the University of South Dakota in 1978. I completed my first two years and initiated a one-year program of independent study with the divisions of Pathology and Pharmacology in an effort to develop improved research skills. I then transferred to The Ohio State Medical School for the completion of my degree in 1981. After completion I entered residency training at Ohio State Hospital Obstetrics and Gynecology residency program in 1983 and completed training in 1987. I then returned to Sioux Falls, SD to begin my practice in OB/GYN in 1987.

During the early years of my practice, I became very involved in the development of Minimally Invasive Surgery and ultimately began teaching other Physicians, with a very good and pioneering group of physicians from all over the US, the newest surgical techniques in surgery. As an extension of this experience I became more involved in development of new laparoscopic surgical improvements for female urinary incontinence. I initiated surgical training for other OB/GYN physicians within my own community of Sioux Falls, SD. As my medical practice moved further in this direction, I then committed entirely to this subspecialty of Urogynecology. Not having had the opportunity to due a formal fellowship in the subspecialty, I engaged many physicians in this area for extended periods of time at their institutions. I also began pursuing a master's degree in Science at the University of South Dakota Medical School to improve my research skills as a medical sub-specialist in this area of medicine. I completed my master's degree in 2011. I was a part of the first group of physicians to become board

certified in the newest subspecialty of Female Pelvic Medicine and Reconstructive Surgery in June 2013. Since that time, I have been involved in six different research projects, one of which involves the use of patient stem cells introduced into the female patient's urethra to correct her urinary stress incontinence.

I am a member of numerous medical societies and have presented research at the International Urogynecology Association meeting at both Como, Italy in 2009 and Lisbon, Portugal in 2011. My memberships are listed in my CV for further reference.

I have been performing pelvic surgery for more than thirty years, and have focused entirely on a surgical practice for the last thirteen years. Over that time I have performed a number of different surgical procedures for a variety of pathologic purposes. Since having begun using the TVT sixteen years ago and the TVT-O some twelve to thirteen years ago, I have estimated that I have placed approximately 2,400 polypropylene mid-urethral slings.

I have published three articles in peer-reviewed journals during my medical career and have been a part of many other research efforts, which are listed in my CV.

II. Urinary Incontinence

Urinary incontinence comes in many different forms. The most common types of female incontinence are:

1) Stress Urinary Incontinence - This form of incontinence involves the loss of urine with events that increase abdominal pressure such as lifting, sneezing, laughing, coughing, or moving from a sitting to a standing position. Losses of urine are usually of small amounts. It is a highly prevalent and often a debilitating and bothersome condition that can negatively affect a woman's quality of life. Between 29%–75% of women, depending on age, have stress incontinence, with a mean of 48%. (Wood and Anger 2014.)

2) Urgency Incontinence - Urge incontinence is the involuntary loss of urine preceded by a sudden urge to pass urine. For these patients, the bladder continues to contract for a few seconds after urine flow begins and the amount of loss can be significant. A subtype of this entity is referred to as Overactive Bladder (OAB).

3) Mixed Incontinence - This is a combination of both Stress and Urge incontinence. This is seen in more the thirty five percent of women over the age of sixty years of age.

4) Overflow Incontinence - This form of incontinence occurs when the bladder's maximum capacity is exceeded. This most commonly occurs in patients with neurologic diseases or spinal cord injuries.

Women are affected in many different ways by the development of urinary incontinence. More than eighteen million women are reported to suffer from some form

of urinary incontinence. The cost of this issue to the health care system in 1995 dollars is reported at thirty two billion dollars with five to six billion spent on diaper-like products alone. We know that fifty percent of nursing home admissions are due to incontinence and that some thirty-five percent of women over the age of sixty years are incontinent. Some thirty-to-forty percent of women over the age of 65 years still living independently are incontinent of urine.

There are many issues that complicate the issues surrounding the development of urinary incontinence. These include a two-times-greater incidence of hip fractures. Hip fractures in women represent the 12th leading cause of death for them. Increased occurrences of urinary tract infection and skin irritation arise. Skin irritation can lead to breakdown of skin and infection. Reports of severe depression requiring treatment are reported in nearly fifty percent of these women. This problem—with or without depressive symptoms—frequently leads to voluntary isolation. This also will often lead to extended hospital stays when being treated for other medical conditions.

III. The Treatment of Stress Urinary Incontinence

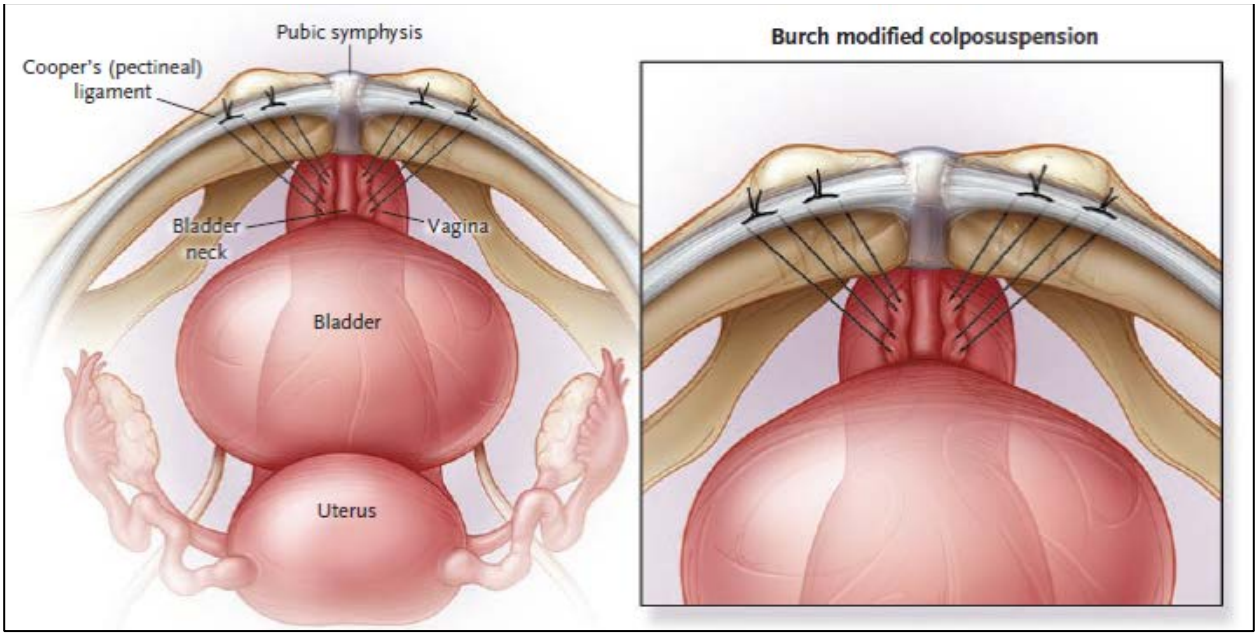
There are both non-surgical and surgical treatments of stress urinary incontinence. Urge incontinence can be treated through the use of anticholinergic and Beta adrenergic medications, but there is no approved pharmaceutical treatment for stress urinary incontinence. (Wood LN and Anger JT, Urinary incontinence in women. BMJ 2014;349:g4531.) Stress urinary incontinence can be treated initially with various lifestyle interventions such as decreasing fluid intake, or decreasing the consumption of caffeinated and carbonated drinks, timed voiding, and weight loss. Pelvic floor muscle training, commonly known as Kegel exercises, can be recommended as well. If lifestyle modifications and Kegel exercises have not cured the patient's stress incontinence, pessaries can be used as well. Pessaries are rubber devices that are placed vaginally, like a birth control diaphragm, and apply pressure to the anterior vaginal wall, thereby supporting the urethra and increasing resistance to urine loss. (Wood and Anger, BMJ 2014.) It has been noted that "incontinence pessaries are modestly effective and are best used for women who are poor surgical candidates or who choose not to have surgery." (Wood and Anger, BMJ 2014.)

The American Urological Association endorses five procedures for the treatment of stress incontinence in women whose incontinence is not resolved by Kegel exercises and who want definitive surgery to cure their stress incontinence: (1) injection of bulking agents; (2) laparoscopic suspensions; (3) mid-urethral slings like the TVT and TVT-O; (4) pubovaginal slings; and (5) open retropubic suspensions. (Wood and Anger, BMJ 2014.)

Bulking agents are chemical agents that are injected into the mid urethra. There is scant data available comparing the various bulking agents now in use. Bulking agents are most often used in patients with "fixed" urethras, a clinical presentation not amenable to mid urethral sling use. One randomized trial comparing the use of buling agents and pubovaginal slings showed that only 9% of the women receiving the bulking agent were objectively cured at six-month follow-up. (Wood and Anger, BMJ 2014

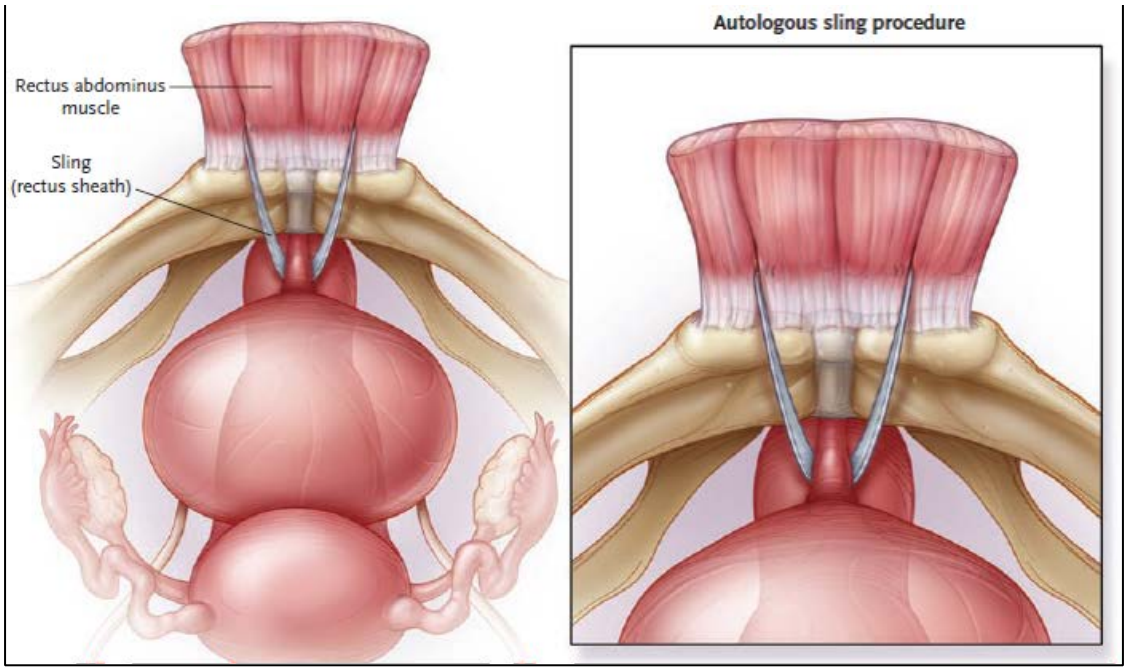
(citing Maher CF, et al., Pubovaginal sling versus transurethral macroplastique for stress urinary incontinence and intrinsic sphincter deficiency: a prospective randomised controlled trial. Br J Obstet Gynecol 2005;112:797-801).)

The Burch procedure involves the suspension of the anterior vaginal wall to Cooper's ligament via sutures. It can be performed laparoscopically or in an open procedure. A Cochrane Review by Lapitan and Cody in 2016 states that "laparoscopic colposuspension should allow speedier recovery [than open colposuspension] but its relative safety and long-term effectiveness is not yet known." (Lapitan MCM and Cody JD, Open retropubic colposuspension for urinary incontinence in women. Cochrane Database of Systematic Reviews 2016, Issue 2. Art. No.: CD002912.) The same authors' Cochrane Review on Burch procedures published in 2012 found that there was no significant difference in incontinence rates between open retropubic colposuspension and midurethral sling procedures. The midurethral sling procedures are much less morbid procedures than open retropubic colposuspension procedures. Some data indicates that the efficacy of the Burch procedure significantly decreases over time. Kjølhede reported in a 14-year follow-up study published in 2005 that 56% of the women treated reported subjectively significant incontinence, and only 19% reported no incontinence episodes. (Kjølhede P, Long-term efficacy of Burch colposuspension: a 14-year follow-up study. Acta Obstet Gynecol Scan 2005;84:767-72.) Alcalay and Stanton reported in a 10-20-year follow-up study of the Burch procedure, that cure rates with the Burch procedure decline for 10–12 years before plateauing at 69%. (Alcalay M and Stanton SL, Burch colposuspension: a 10-20 year follow up. Br J Obstet Gynaecol. 1995 Sep;102:740-45.) The illustration below—from the SISTEr study—depicts the Burch colposuspension:



Autologous fascial sling procedures utilize the patient's own tissue—either rectus fascia or fascia lata—as a sling material. The fascia used as the graft material is harvested from the patient via an abdominal incision (in the case of rectus fascia) or

lateral thigh incision (in the case of fascia lata). This exposes the patient to a risk of wound complications or herniation in connection with those operative sites. Once the graft is harvested from the patient, the strip of fascia is placed transvaginally, securing it superiorly to the rectus fascia. (Wood and Anger, BMJ 2014.) The illustration below—from the SISTEr study—depicts the autologous fascial sling surgery:



In 2007, a group of surgeons published in the New England Journal of Medicine a multicenter, randomized clinical trial comparing the autologous fascial sling surgery with the Burch colposuspension for the treatment of stress urinary incontinence in 655 women. At two-year follow-up, 66% of the pubovaginal sling patients had their SUI cured, and only 49% of the Burch patients did. Adverse events occurred in 63% of the pubovaginal sling patients and 47% of the Burch patients. Voiding dysfunction occurred in 14% of the pubovaginal sling patients and 2% of the Burch patients. 27% of the sling patients had post-operative urge incontinence, whereas 20% of the Burch patients did. At two-year follow-up, 86% of the pubovaginal sling patients were satisfied with their procedure and 78% of the Burch patients were. (Albo ME, et al., Burch Colposuspension versus Fascial Sling to Reduce Urinary Stress Incontinence. N Eng J Med. 2007 May;356(21):2143-55.) 482 of the patients were followed for a minimum of five years to assess their continence, and the authors found that continence rates were lower in the Burch group (24.1%) than in the fascial sling group (30.8%). (Brubaker L, et al., 5-Year Continence Rates, Satisfaction and Adverse Events of Burch Urethropexy and Fascial Sling Surgery for Urinary Incontinence. J. Urol. 2012 Apr;187:1324-30.)

Other surgical procedures used to treat stress incontinence include the anterior colporrhaphy, Kelly plication, and Marshall Marchetti Krantz procedure. The poor efficacy rates associated with these procedures has resulted in them now being rarely performed as a primary procedure for stress incontinence. The anterior colporrhaphy is a procedure performed vaginally. It is frequently performed in combination with other

vaginal surgery for pelvic organ prolapse. The Kelly-Kennedy plication is frequently used in combination with the anterior repair to potentially improve anti-incontinence effect. Neither of these procedures are now used as primary procedures of urinary stress incontinence. The Marshall-Marchetti-Krantz is a retropubic procedure performed either open or via laparoscopy. This procedure has led to frequent voiding dysfunction and occasional osteitis pubis (an infection of the pubic bone). Its long-term efficacy has been less than 50% and due to the increased morbidity this procedure is very infrequently used today.

i. Mid-urethral slings generally

In the late '90s, the TVT sling was introduced and revolutionized the surgical treatment of stress urinary incontinence. Rather than supporting the urethra at the urethrovesical junction, mid urethral slings—as their name suggests—provide support at the mid-urethra.

IV. Ethicon's TVT Device

a. The Development of the TVT

The first retropubic mid-urethral sling was developed by Dr. Ulf Ulmsten and colleagues in the mid-1990s, but the work that led to the first TVT led back to the '70s or '80s. Disappointed with the morbidity, invasiveness, and unpredictable results of existing anti-incontinence procedures, Ulmsten and colleagues sought a new way to treat stress incontinence. Rather than supporting the bladder neck, they put a graft at the mid-urethra. (Nilsson Podcast Transcript.) After initially using Mersilene tape to develop a prototype using cadavers and animal testing, Ulmsten and colleagues discovered that, while Mersilene was easy to use, non-stretch, and effective, it had a high erosion rate of 14%. As a result, they decided to use polypropylene, which "had solved the problem of erosions and become universally accepted." (Petros P, Creating a gold standard surgical device: scientific discoveries leading to TVT and beyond. Int Urogynecol J 2015.) What was initially known as the intravaginal slingplasty eventually became the Gynecare TVT (tension-free vaginal tape) device after Dr. Axel Arnaud of Ethicon met with Dr. Ulmsten in 1995 and worked to purchase the technology on behalf of Ethicon and bring it to the world. (Arnaud A, The history of TVT.)

The TVT consists of a 1.1 x 45 cm strip of Prolene polypropylene mesh that is attached to stainless steel trocars used during implantation of the mesh. The mesh is covered by plastic sheaths that facilitate smooth passage of the mesh through the tissues during implantation. The mesh is macroporous (Type I) monofilament mesh that is made of Prolene polypropylene suture material. The pores are 1,379 µm and the mesh weighs 100 g/m2. (Moalli P, et al., Tensile properties of five commonly used mid-urethral slings relative to the TVT. Int Urogynecol J. 2008;19:655-63.) It can be implanted in a "bottom-up" or "top-down" configuration depending on surgeon preference, but is more commonly implanted using a bottom-up method, starting with a mid-urethral incision, dissection of a retropubic tract for the trocar passage, and exiting through two small suprapubic incisions. In 1996, Dr. Ulmsten and colleagues reported

an 84% cure rate with the TVT sling at two years' follow-up. (Ulmsten U, et al., An Ambulatory Surgical Procedure Under Local Anesthesia for Treatment of Female Urinary Incontinence. Int Urogynecol J. 1996;7:81-86.)

b. The Development of the TVT-Obturator

The TVT-Obturator device was initially developed by Dr. Jean de Leval in Belgium, as a modification of Dr. Delorme's trans-obturator sling passage. (Delorme E, Trans-obturator tape: a mini invasive procedure for the treatment of female stress urinary incontinence. Progress in Urology 2001.) It was an inside-out (or medial-to-lateral) sling passage technique, unlike Delorme's outside-in (or lateral-to-medial) passage technique. (de Leval J, Novel Surgical Technique for the Treatment of Female Stress Urinary Incontinence: Transobturator Vaginal Tape Inside-Out. Eur Urol 2003;44:724-30.) Rather than supporting the mid-urethra in a u-shaped configuration and exiting the body via suprapubic incisions, the TVT-Obturator sling passes through the obturator foramen and exits through small incisions in the medial thigh. While de Leval recognized that the TVT "has probably been the most revolutionary" surgical technique developed to cure SUI, he sought to avoid or reduce the rate of bladder perforation, temporary or persistent retention, pain, urinary infection, and de novo instability by using a transobturator tape passage route. (de Leval 2003.)

The TVT-O is made of the same macroporous, monofilament, lightweight Prolene mesh as the TVT device, and is also 1.1 x 45 cm and covered by a plastic sheath. Rather than being attached to curved trocars, the mesh in the TVT-O is attached to two stainless steel helical passers with plastic handles. A Gynecare TVT Atraumatic Winged Guide—a stainless steel accessory instrument—is used to facilitate passage of the helical passers through the dissection tract. Based on the success of the TVT device and Dr. de Leval's results in his early study, Ethicon's Dr. Arnaud worked with Dr. de Leval to acquire the technology for Ethicon and bring the TVT-O device to market. (Arnaud A, History of TVT-O.) The device was launched in early 2004, and by early 2007, had been performed in hundreds of thousands of women.

c. Efficacy and Safety of the Devices

The TVT and TVT-O devices were quickly embraced by surgeons, who recognized the devices' advantages over prior procedures such as the Burch urethropexy, the autologous fascial sling procedure, and the Marshall-Marchetti-Krantz procedure. Since their introduction, the devices have been extensively studied.

The TVT device is the most studied mid urethral sling, and has been the subject of more than 100 randomized controlled trials, which are second only to meta-analyses and systematic reviews, in terms of quality of scientific evidence. (Ethicon Tension-Free Midurethral Sling: Market Update, ETH.MESH.10281865; Oxford Levels of Evidence Pyramid.) In 2002, Drs. Karen Ward and Paul Hilton published the results of their landmark multi-center prospective, randomized trial comparing TVT and the Burch procedure. 175 women received the TVT, and 169 received a Burch procedure. They found that there was no significant difference between the two groups in terms of the

objective cure rate (66% of the TVT patients and 57% in the Burch group). There were more bladder injuries in the TVT group, but postoperative complications, especially delayed resumption of micturition, were more common after the Burch procedure. They also noted that operative time, hospital stay, and return to normal activities was longer in the Burch group. (Ward K and Hilton P, Prospective multicenter randomised trial of tension-free vaginal tape and colposuspension as primary treatment for stress incontinence. BMJ. 2002 Jul 13;325(7355):67.) At five-year follow-up, they found that there was no difference between TVT and colposuspension in terms of cure rates; the effect of both procedures on cure of incontinence and improvement in quality of life is maintained in the long term. (Ward KL and Hilton P, Tension-free vaginal tape versus colposuspension for primary urodynamic stress incontinence: 5-year follow-up. BJOG 2008;115:226-33.)

The device has been studied in many long-term studies, even out to seventeen years after the surgery, and the studies support the safety and efficacy of the device. (Nilsson CG, et al., Seventeen years' follow-up of the tension-free vaginal tape procedure for female stress urinary incontinence. Int Urogynecol J 2013 Aug;24(8):1265–1269; Nilsson CG, et al., Eleven years prospective follow-up of the tention-free vaginal tape procedure for treatment of stress urinary incontinence. Int Urogynecol J 2008;19:1043-47; Liapis A, et al., Long-term efficacy of tension-free vaginal tape in the management of stress urinary incontinence in women: efficacy at 5- and 7-year follow-up. Int Urogynecol J 2008 Nov;19(11):1509-1512; Olsson I, et al., Long-term efficacy of the tension-free vaginal tape procedure for the treatment of urinary incontinence: a retrospective follow-up 11.5 years post-operatively. Int Urogynecol J 2010 Jun;21(6):679–683; Groutz A, et al., Ten-Year Subjective Outcome Results of the Retropubic Tension-Free Vaginal Tape for Treatment of Stress Urinary Incontinence. J Minim Invasive Gynecol 2011;18:726-29; Aigmueller T, et al., Ten-year follow-up after the tension-free vaginal tape procedure. Am J Obstet Gynecol 2011 Nov;205(5):496.e1-5; Heinonen P, et al., Tension-free vaginal tape procedure without preoperative urodynamic examination: long-term outcome. Int J Urol. 2012 Nov;19(11):1003-9; Serati M, et al., TVT for the Treatment of Urodynamic Stress Incontinence: Efficacy and Adverse Effects at 13-Year Follow-Up, Neurourol and Urodyn 2017 Jan;36(1):192-197; Serati M, et al., Tension-free Vaginal Tape for the Treatment of Urodynamic Stress Incontinence: Efficacy and Adverse Effects at 10-Year Follow-Up. Eur Urol 2012;61:939-46; Svenningsen R, et al., Long-term follow-up of the retropubic tension-free vaginal tape procedure. Int Urogynecol J. 2013 Aug;24(8):1271-8.)

The TVT-O has also been studied in several intermediate- and long-term studies which support the safety and efficacy of the device. (Liapis A, et al., Efficacy of inside-out transobturator vaginal tape (TVTO) at 4 years follow up. 2010;148:199–201; Angioli R, et al., Tension-Free Vaginal Tape Versus Transobturator Suburethral Tape: Five-Year Follow-up Results of a Prospective, Randomised Trial. Eur Urol 2010;58:671–677; Groutz A, et al., Long-Term Outcome of Transobturator Tension-Free Vaginal Tape: Efficacy and Risk Factors for Surgical Failure. J of Women's Health 2011;20(10):1525–1528; Cheng D, et al., Tension-free vaginal tape-obturator in the treatment of stress urinary incontinence: a prospective study with five-year follow-up. Eur J Obstet Gynecol

Reprod Biol 2012;161:228–231; Serati M, et al., TVT-O for the Treatment of Pure Urodynamic Stress Incontinence: Efficacy, Adverse Effects, and Prognostic Factors at 5-Year Follow-up. Eur Urol 2013;63:872–78; Laurikainen E, et al., Five-year Results of a Randomized Trial Comparing Retropubic and Transobturator Midurethral Slings for Stress Incontinence. Eur Urol 2014 Jun;65(6):1109–14; Athanasiou S, et al., Seven years of objective and subjective outcomes of transobturator (TVT-O) vaginal tape: Why do tapes fail? 2014;25:219–225.) In 2010, Dr. Holly Richter and colleagues published the results of their multicenter, randomized equivalence trial comparing retropubic midurethral sling outcomes with transobturator midurethral sling outcomes. The study involved 597 women with stress incontinence. They observed an 80.8% success rate in the retropubic sling group and a 77.7% success rate in the transobturator group. In terms of subjective success, they found rates of 62.2% for retropubic slings and 55.8% for transobturator slings. There were no significant differences between the groups in the rates of postoperative urge incontinence, satisfaction with the procedure, or quality of life. (Richter HE, et al., Retropubic versus Transobturator Midurethral Slings for Stress Incontinence. N Engl J Med 2010;362;22:2066-76.)

Ashley Cox, Sender Herschorn and Livia Lee published an article titled “Surgical management of female SUI: is there a gold standard?” in 2013. They noted that “the traditional gold standards of Burch retropubic colposuspension and pubovaginal slings are still appropriate treatment options for some patients, but randomized controlled trials have demonstrated that synthetic midurethral slings are just as effective as these traditional procedures but with less associated morbidity. Thus, midurethral slings—inserted via a retropubic or transobturator approach—have become the new gold standard first-line surgical treatment for women with uncomplicated SUI.” They found that retropubic slings have slightly higher success rates than transobturator slings, but more post-operative complications. They concluded: “Based on the literature a new gold standard first-line surgical treatment for women with SUI is the synthetic midurethral sling inserted through a retropubic or transobturator approach.” (Cox A, et al., Surgical management of female SUI: is there a gold standard? Nat. Rev. Urol. 2013;10:78-89.)

Drs. Cecile A. Unger, Anthony E. Rizzo, and Beri Ridgeway published a study in the International Urogynecology Journal in 2016 titled “Indications and risk factors for midurethral sling revision.” They did a case-control study of all women undergoing midurethral sling placement for SUI over a 10-year period. They studied 3,307 women who had a midurethral sling, and found that 89 of the women (2.7%) had a sling revision procedure for one of the following indications: urinary retention (43.8%), voiding dysfunction (42.7%), recurrent UTI (20.2%), mesh erosion (21.3%), vaginal pain/dyspareunia (7.9%), and groin pain (3.4%). They also found that the type of sling placed was not associated with indication for revision. (Unger CA, et al., Indications and risk factors for midurethral sling revision. Int Urogynecol J. 2016 Jan;27(1):117-22.)

Michele Jonsson Funk and colleagues conducted a population-based cohort study of commercially insured women 17 or older who underwent a midurethral sling procedure during a 10-year period. They identified 188,454 women who had undergone the sling procedures and found that the 9-year cumulative risk of sling revision/removal

was only 3.7%. They found the 9-year risk of sling revision or removal for mesh erosion was 2.5%. The majority of revision/removals occurred within the first four years following the implant surgery. (Jonsson Funk M, et al., Sling revision/removal for mesh erosion and urinary retention: long-term risk and predictors. Am J Obstet Gynecol 2013;208:73.e1-7.)

In 2013, Dr. Blayne Welk and colleagues published a population-based retrospective cohort study that included all adult women in Ontario, Canada from 4/1/02 thorugh 12/31/12 who underwent a surgery for SUI with synthetic mesh. They sought "[t]o measure the incidence of mesh removal or revision after SUI procedures and to determine whether significant surgeon and patient risk factors exist." Their study included 59,887 women. They found that the 10-year cumulative incidence of complications being treated was 3.29%. High-volume surgeons' patients had a significantly lower risk for experiencing their composite outcome of the first reoperation for SUI mesh-related complications. (Welk B, et al., Removal or Revision of Vaginal Mesh Used for the Treatment of Stress Urinary Incontinence. JAMA Surg. 2015 Dec;150(12):1167-75.)

In 2012, Dr. John N. Nguyen and colleagues conducted an analysis of all female members of Kaiser Permanente Southern and Northern California and Hawaii who underwent sling procedures or pelvic organ prolapse surgeries using implanted grafts or mesh between 9/1/08 and 5/31/10 in order to estimate the perioperative complication and reoperation rates associated with the use of mesh and biologic grafts. The study included 4,142 women who underwent 3,747 sling procedures. The authors found that mesh-related reoperations following sling procedures occurred in 2.4% of retropubic sling cases (55 of 2,339) and in 2.9% of transobturator sling cases (23 of 794). Only 0.8% of the retropubic sling patients had a reoperation for excision of a vaginal mesh exposure in 0.9% of retropubic sling patients and 1% of transobturator sling patients. Only 1 patient out of 2,339 had an excision of a retropubic sling for pain (0.04%), and none of the transobturator patients did. (Nguyen JN, et al., Perioperative Complications and Reoperations After Incontinence and Prolapse Surgeries Using Prosthetic Implants, Obstet Gynecol 2012 Mar;119(3):539-46.)

Drs. Ford, Rogerson, Cody, and Ogah published a Cochrane Review of mid-urethral sling operations for stress urinary incontinence in women in 2015, which analyzed 81 studies evaluating 12,113 women. The authors concluded as follows:

> *Mid-urethral sling operations have been the most extensively researched surgical treatment for stress urinary incontinence (SUI) in women and have a good safety profile. Irrespective of the routes traversed, they are highly effective in the short and medium term, and accruing evidence demonstrates their effectiveness in the long term. This review illustrates their positive impact on improving the quality of life of women with SUI.*

(Ford AA, et al., Mid-urethral sling operations for stress urinary incontinence in women. Cochrane Database Syst Rev. 2015 Jul 1;(7):CD006375.) They noted that the overall rate of vaginal tape erosion/exposure/extrusion was low in both groups—2.1% for

retropubic slings like the TVT and 2.4% for transobturator slings like the TVT-O. They also noted that the studies showed there was significant improvement in sexual function from baseline scores for both retropubic and transobturator slings, with no significant differences between the groups. At 24-month follow-up, "rates of superficial and deep dyspareunia were low, with no difference between the groups."

Drs. Ogah, Cody, and Rogerson published a short-version Cochrane Review on midurethral sling operations in 2011, which analyzed 62 trials involving 7,101 women. They found that midurethral sling operations appeared to be as effective as traditional suburethral slings, but with shorter operating time, and less post-operative voiding problems or de novo urgency symptoms. They also found that midurethral slings appeared to be as effective as open retropubic colposuspension, but with fewer perioperative complications, less post-operative voiding problems, shorter operating time, and reduced hospital stay, but with significantly more bladder perforations. It was noted that midurethral sling procedures had significantly less de novo urgency and urgency incontinence, shorter operating time, hospital stay, and return to daily activities. The authors found that a retropubic bottom-to-top route was more effective than top-to-bottom route, with significantly less voiding dysfunction, bladder perforations, and mesh erosions. They found that monofilament tapes (like the TVT and TVT-O) had significantly higher objective cure rates compared with multifilament tapes, with fewer tape erosions. They found transobturator slings to be less favorable in terms of objective cure, but not in terms of subjective cure. Transobturator tapes had less voiding dysfunction, blood loss, bladder perforation, and a shorter operating time. (Ogah J, et al., Minimally Invasive Synthetic Suburethral Sling Operations for Stress Urinary Incontinence in Women: A Short Version Cochrane Review. Neurourol and Urodyn. 2011;30:284-91.)

Dr. Giovanni A. Tommaselli and colleagues published a systematic review and meta-analysis of medium-and long-term outcomes following midurethral sling placement for SUI treatment in 2015. They found that retropubic and transobturator midurethral slings had similar objective cure rates, but retropubic slings had higher subjective cure rates. Bladder injuries occurred more frequently with retropubic slings. The rate of vaginal erosion was not different between the transobturator and retropubic sling groups. Out of a total of 3,974 retropubic patients, only 13 (0.3%) had persistent or chronic pain. Out of 2,432 transobturator sling patients, only 30 (1.2%) had persistent or chronic pain. (Tommaselli GA, et al., Medium-term and long-term outcomes following placement of midurethral slings for stress urinary incontinence: a systematic review and metaanalysis. Int Urogynecol J 2015 Sep;26(9):1253-68.)

Dr. Megan O. Schimpf and others associated with the Society of Gynecologic Surgeons Systematic Review Group published a systematic review and meta-analysis of RCTs with a minimum of one year of follow-up comparing a sling procedure for SUI to another sling or the Burch urethropexy. The study was published in 2014 in the American Journal of Obstetrics & Gynecology. Table 3 in the study lists the summary estimates of the incidence of various complications associated with anti-incontinence procedures, and shows that the retropubic and transobturator slings like the TVT and TVT-O compare favorably to non-mesh pubovaginal sling procedures or the Burch

procedure. For example, the authors reported the following summary estimates of incidence for complications, among others:

	Retropubic MUS	***Transobturator MUS***	***Burch***	***Pubovaginal Sling***
Transfusion	0.40%	0.17%	0.00%	1.9%
Hematoma	0.88%	0.59%	1.4%	2.2%
Dyspareunia	0.00%	0.16%	Not Reported (NR)	0.99%
Return to OR for Erosion	1.9%	2.7%	0.28%	1.6%
Exposure	1.4%	2.2%	0.00%	5.4%
Wound Infection	0.75%	0.74%	7.0%	2.6%
UTI	11%	4.3%	5.9%	4.2%
Bowel Injury	0.34%	0.00%	3.13%	NR
OAB/Urgency	6.9%	5.3%	4.3%	8.6%
Retention Lasting > 6 Weeks	2.7%	2.4%	7.6%	7.5%
Return to OR for Urinary Retention	1.2%	1.1%	0.00%	3.0%
Groin Pain	1.5%	6.5%	1.10%	0.34%
Leg Pain	0.62%	16%	NR	NR

Bladder Perforation	3.6%	0.70%	2.8%	2.3%

(Schimpf MO, et al, Sling surgery for stress urinary incontinence in women: a systematic review and metaanalysis. Am J Obstet Gynecol. 2014 Jul;211(1):71.e1-71.e27.)

Based on their overall analysis, the SGS Systematic Review Group concluded that, for women considering either a midurethral sling or the Burch procedure, they suggested either intervention for objective and subjective cure, with the decision to be based on which adverse events are of greatest concern to the patient and whether any concomitant procedures were planned. For women considering pubovaginal sling versus the TVT, they recommended the TVT for better subjective cure outcomes. And between retropubic and transobturator midurethral slings, they recommended either intervention for objective and subjective cure, with the decision again, to be based on which adverse events are of greatest concern to the patient.

A 2008 systematic review and meta-analysis by Novara and colleagues found that complication rates were similar after the TVT and Burch procedures except for bladder perforation (more common with TVT) and reoperation rate (more common after Burch. They found that the TVT and pubovaginal sling procedures had similar complication rates. Their comparison of retropubic and transobturator tapes showed that bladder perforations, hematoma, and storage lower urinary tract symptoms was significantly less common following transobturator tape procedures. The overall rate of vaginal erosion was 1.1%. (Novara G, et al., Complication Rates of Tension-Free Midurethral Slings in the Treatment of Female Stress Urinary Incontinence: A Systematic Review and Meta-Analysis of Randomized Controlled Trials Comparing Tension-Free Midurethral Tapes to Other Surgical Procedures and Different Devices. Eur Urol. 2008;53:288-309.)

In 2017, Dr. Dorothy Kammerer-Doak and colleagues published the results of a survey of IUGA members on practice patterns in treating SUI and pelvic organ prolapse. 564 members answered the survey, which revealed that the preferred method of treatment for uncomplicated SUI is the transobturator midurethral sling (49.7%) followed by the retropubic midurethral sling (34.8%). The Burch procedure was preferred by only 3.7% of respondents. For recurrent SUI after failure of an initial procedure, retropubic midurethral slings are the most commonly used treatment. (Kammerer-Doak D, et al., Variability in practice patterns in stress urinary incontinence and pelvic organ prolapse: results of an IUGA survey. Int Urogynecol J. 2016 Oct 17 [Epub ahead of print].)

The American Urogynecologic Society (AUGS) and the Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction (SUFU) issued their Position Statement on Mesh Midurethral Slings for Stress Urinary Incontinence in 2014. In that statement, the organizations stated: “The polypropylene mesh midurethral sling is the recognized worldwide standard of care for the surgical treatment of stress urinary incontinence. The procedure is safe, effective, and has improved the quality of life for

millions of women." (AUGS/SUFU Position Statement 2014.) Other points made by AUGS and SUFU in their statement include:

> *Polypropylene material is safe and effective as a surgical implant. Polypropylene material has been used in most surgical specialties (including general surgery, cardiovascular surgery, transplant surgery, ophthalmology, otolaryngology, gynecology, and urology) for over five decades, in millions of patients in the US and the world (personal communication with manufacturers of polypropylene suture and mesh). As an isolated thread, polypropylene is a widely used and durable suture material employed in a broad range of sizes and applications. As a knitted material, polypropylene mesh is the consensus graft material for augmenting hernia repairs in a number of areas in the human body and has significantly and favorably impacted the field of hernia surgery. As a knitted implant for the surgical treatment of SUI, macroporous, monofilament, light weight polypropylene has demonstrated long term durability, safety, and efficacy up to 17 years.*
>
> *A broad evidence base including high quality scientific papers in medical journals in the US and the world supports the use of the MUS as a treatment for SUI. There are greater than 2000 publications in the scientific literature describing the MUS in the treatment of SUI. These studies include the highest level of scientific evidence in the peer reviewed scientific literature. The MUS has been studied in virtually all types of patients, with and without comorbidities, and all types of SUI. Multiple randomized, controlled trials comparing types of MUS procedures, as well as comparing the MUS to other established non-mesh SUI procedures, have consistently demonstrated its clinical effectiveness and patient satisfaction. Among historical SUI procedures, the MUS has been studied as long in follow-up after implantation as any other procedure and has demonstrated superior safety and efficacy. No other surgical treatment for SUI before or since has been subject to such extensive investigation.*
>
> *Since the publication of numerous level one randomized comparative trials, the MUS has become the most common surgical procedure for the treatment of SUI in the US and the developed world. This procedure has essentially replaced open and transvaginal suspension surgeries for uncomplicated SUI. There have been over 100 surgical procedures developed for the management of SUI and there is now adequate evidence that the MUS is associated with less pain, shorter hospitalization, faster return to usual activities, and reduced costs as compared to historic options that have been used to treat SUI over the past century. Full-length midurethral slings, both retropubic and transobturator, have been extensively studied, are safe and effective relative to other treatment options and remain the leading treatment option and current gold standard for stress incontinence surgery. Over 3 million*

> *MUS have been placed worldwide and a recent survey indicates that these procedures are used by > 99% of AUGS members.*

(AUGS Position Statement on Mesh Midurethral Slings for Stress Urinary Incontinence 2014.)

In March 2016, AUGS reached out to numerous medical societies to solicit their support for the position statement, which led to the following organizations signing on as supporting organizations to the position statement, which was updated in June 2016: The American College of Obstetricians and Gynecologists (ACOG), The Society of Gynecologic Surgeons (SGS), The American Association of Gynecological Laparoscopists (AAGL), American Urological Association (AUA), The National Association for Continence (NAFC), and Women's Health Foundation (WHF). (Hale E-mail, President's Perspective: Organizations Lend their Support to Mid-urethral Slings, 6/23/16.)

In November 2015, ACOG and AUGS issued a Practice Bulletin Summary regarding Urinary Incontinence in Women, which provided clinical management guidelines for obstetrician-gynecologists. That bulletin provides as follows:

> *Synthetic midurethral slings demonstrate efficacy that is similar to traditional suburethral fascial slings, open colposuspension, and laparoscopic colposuspension. Compared with suburethral fascial slings, fewer adverse events have been reported with synthetic midurethral slings. Voiding dysfunction is more common with open colposuspension than with synthetic midurethral slings.*
>
> *There are substantial safety and efficacy data that support the role of synthetic mesh midurethral slings as a primary surgical treatment option for stress urinary incontinence in women.*

(ACOG & AUGS, Urinary Incontinence in Women, Practice Bulletin Summary No. 155, Nov. 2015.) The International Continence Society issued a Fact Sheet in 2015 that noted: "Worldwide, midurethral slings comprised of synthetic mesh have become the treatment of choice for SUI. Long-term data are robust and demonstrate durable efficacy with a very low complication rate, particularly in experienced hands." (International Continence Society, Fact Sheet – A Background to Urinary and Faecal Incontinence, Aug. 2015.) The International Urogynecological Association has also issued a Position Statement on Mid-Urethral Slings for Stress Urinary Incontinence. In that statement, IUGA noted as follows:

> *[Mid-urethral slings] have been shown to be as effective as more invasive traditional surgery with major advantages of shorter operating and admission times, and a quicker return to normal activities together with lower rates of complications. This has resulted in MUS becoming the operation of choice in Europe, Asia, South America, South Africa,*

> *Australasia and North America for treatment of SUI with several million procedures performed worldwide.*
>
> * * * *
>
> *There is robust evidence to support the use of MUS from over 2,000 publications making this treatment the most extensively reviewed and evaluated procedure for female stress urinary incontinence now in use. These scientific publications studied all types of patients, including those with co-morbidities such as prolapse, obesity and other types of bladder dysfunction. It is, however, acknowledged that any operation can cause complications. For MUS these include bleeding, damage to the bladder and bowel, voiding difficulty, tape exposure and pelvic pain; all of these may require repeat surgery but this is uncommon. Nevertheless, the results of a recent large multi-centre trial have confirmed excellent outcomes and a low rate of complications to be expected after treatment with MUS. Additionally, long term effectiveness of up to 80% has been demonstrated in studies including one which has followed up a small group of patients for 17 years.*
>
> *As a result, IUGA supports the use of monofilament polypropylene mid-urethral slings for the surgical treatment of female stress urinary incontinence.*

(IUGA Position Statement on Mid-Urethral Slings for Stress Urinary Incontinence, Jul. 2014.)

d. Advantages of the TVT and TVT-O Devices

The TVT and TVT-O devices have many advantages over their predecessor anti-incontinence procedures. They involve shorter operating time than traditional native tissue repairs, less anesthesia, they are less invasive, they have lower complication rates, quicker return to activities, lower recurrence rates, and as a result, are considered the current gold standard treatment for stress urinary incontinence. The procedures are straightforward to perform, which broadens the number of surgeons able to perform the procedures, which, in turn, broadens the number of women with access to treatment. They use very small incisions, which reduces recovery time and post-operative pain. The mesh material is readily available, well-known for its biocompatibility, and does not pose a risk of disease transmission like xenografts or allografts do. The design of the mesh allows for good tissue ingrowth while still allowing for the entry of macrophages to eradicate any bacteria present. The fact that the slings are anchorless reduces the pain, voiding problems, and anchor-point problems associated with anchored slings. It is also an advantage of the procedures that continence can be tested during the procedure. The surgeries are performed by following anatomic landmarks that allow for safe passage of the trocars, and the risk of infection is low. (Schimpf 2014, Table 3.)

f. Plaintiffs' Experts' Contentions

Plaintiffs' expert witnesses in this litigation have contended that the slings are cytotoxic, they shrink or contract, they are potentially carcinogenic, they degrade, they rope, curl, lose parties, fray, and create an excessive foreign body reaction. They also contend that the mesh is heavyweight and small-pore, and that this creates adverse reactions in patients including pain, erosions, an excessive foreign body reaction, and scar plating. I have not observed these alleged characteristics in my practice, and systematic reviews, meta-analyses, and RCTs regarding the slings do not mention any of these alleged characteristics.

i. Cytotoxicity and Foreign Body Reaction

Plaintiffs' experts contend that because an in vitro test Ethicon conducted showed evidence of causing cell lysis or toxicity in vitro (ETH.MESH.08476311), the mesh used in the TVT and TVT-O slings is cytotoxic and harming women. In vitro tests, however, are not always directly translatable into clinically significant findings. Indeed, Ethicon properly recognized that "[t]he assessment of biocompatibility of a medical device must take into consideration all available data including clinical data which is most relevant." (ETH.MESH.00349228.) As explained above, there is an extensive body of scientific data from clinical studies showing a lack of cytotoxicity. If the mesh in the slings was cytotoxic, the literature would not present the very favorable data it does. The Ford 2015 Cochrane Review notes that Type I mesh like the mesh in the TVT and TVT-O devices "has the highest biocompatibility with the least propensity for infection." I have observed no cytotoxic effects from implantation of the mesh in my clinical practice.

ii. Shrinkage/Contraction

The TVT and TVT-O slings do not shrink or contract. Scar tissue can shrink or contract during the normal healing process, and scar tissue that grows into the pores of the TVT or TVT-O devices following implantation can shrink or contract, but again, clinically significant contraction or shrinkage is not seen in the literature. The 17-year follow-up study by Nilsson specifically noted: "An important observation is that there seems to be no shrinkage of the TVT mesh over time, as suggested by PVR volumes within normal ranges, except for 2 patients with concomitant diseases (Parkinson's, grade III cystocele)." (Nilsson CG, et al., Seventeen years' follow-up of the tension-free vaginal tape procedure for female stress urinary incontinence. Int Urogynecol J 2013 Aug;24(8):1265–1269.) In 2003, Drs. Emily S. Lukacz, Karl M. Luber, and Charles W. Nager published the results of their prospective longitudinal evaluation of the effects of the TVT on proximal urethral position and found that "there appears to be no shrinkage or tightening of the sling." (Lukacz ES, et al., The effects of the tension-free vaginal tape on proximal urethral position: a prospective longitudinal evaluation. Int Urogynecol J. 2003;14:179-84.) Lo and colleagues conducted an ultrasound assessment of women who under went a TVT surgery three years after the surgery and found that the tape position and characteristics suggested "that shrinkage and compromise of the TVT sling does not occur." (Lo T-S, et al., Ultrasound Assessment of Mid-Urethra Tape at Three-Year Follow-Up After Tension-Free Vaginal Tape Procedure. J Urol 2004;63(4):671-5.) In 2003, Dr. Hans Peter Dietz and colleagues published an observational ultrasound

study to study potential shrinkage of the sling, and they found that the "TVT does not seem to contract or shorten over a median observation period of 1.6 years. On the contrary, it appears to slowly migrate caudally." (Dietz HP, et al., Does the tension-free vaginal tape stay where you put it? Am J Obstet Gynecol 2003;188:950-3.) These studies are consistent with my clinical experience using the slings. I do not see widespread urinary retention that would suggest the slings are shrinking. While post-operative urinary retention is a potential outcome of any anti-incontinence procedure, it occurs infrequently with the TVT and TVT-O. The 2015 Cochrane Review, for instance, found that the rate of urinary retention was 1.6% for retropubic slings and 0.5% for transobturator slings, and the 2014 SGS systematic review and meta-analysis found that the rate of urinary retention lasting more than six weeks was only 2.7% with retropubic midurethral slings and 2.4% with transobturator slings.

iii. Carcinogenesis

The available scientific evidence soundly rejects the notion that the TVT or TVT-O mesh is cytotoxic. Dr. Brian J. Linder and colleagues at the Mayo Clinic published the results of their study of 2,474 patients undergoing polypropylene MUS placement designed to evaluate the potential carcinogenesis of the midurethral sling mesh. They found, "in a large series of patients undergoing synthetic midurethral sling placement with long-term follow-up, no evidence of an association between mesh placement with subsequent local cancer formation." (Linder BJ, et al., Evaluation of the local carcinogenic potential of mesh used in the treatment of female stress urinary incontinence. Int Urogynecol J. 2016 Sep;27(9):1333-6.) In 2014, Dr. Pamela Moalli and colleagues published a commentary piece reviewing the available information regarding the response to polypropylene by the human body. They noted that "it is well known that tumor formation related to biomaterials in animals is largely dependent on the physical, not the chemical configuration of the implant, with smooth large surface areas (discs and thin sheets) being carcinogenic, and irregular disrupted surfaces (e.g., those that contain pores as in meshes) lacking significant carcinogenicity." I agree with the following statement those authors made in the conclusion of their commentary:

> *It would be a tragedy for women worldwide if nonscientifically based articles regarding the potential hazards of polypropylene incited a spiraling course for the best (highest success rate and minimal morbidity) surgical procedure developed to date for stress urinary incontinence simply because of liability concerns by doctors, hospitals, and manufacturers. As treating physicians, we must let science and clinical studies determine our practice. More importantly, we must align with the millions of women who have been successfully treated with mesh with absolutely no evidence of systemic complications (including cancer) and who have regained control of their quality of life.*

(Moalli P, et al., Polypropylene mesh: evidence for lack of carcinogenicity. Int Urogynecol J. 2014 May;25(5):573-6.)

iv. Degradation

It has also been suggested that the polypropylene degrades in the human body, leading to an intense inflammatory reaction, pain, erosions, and other problems. I have seen scanning electron microscope images of explanted polypropylene and Prolene that shows surface cracking, but based on my experience using the devices and literature discussing this subject, it is my opinion that the surface cracking seen in such images is not degradation of the polypropylene or Prolene, but cracking of a protein-based biofilm on the surface of the mesh. Drs. Renaud de Tayrac and Vincent Letouzey published a study in which they showed scanning electron microscope photos of a lightweight, macroporous, monofilament knitted polypropylene mesh like the TVT and TVT-O mesh that was explanted after 30 days with infection by E. coli. The initial photo (A) shows surface cracking on a strand of polypropylene, but then subsequent photos show that after the mesh was washed with DMSO the cracked biofilm begins to slough off the filament of polypropylene (B) and when the mesh was ultrasonically shocked, the biofilm was removed and no polymer degradation was seen.

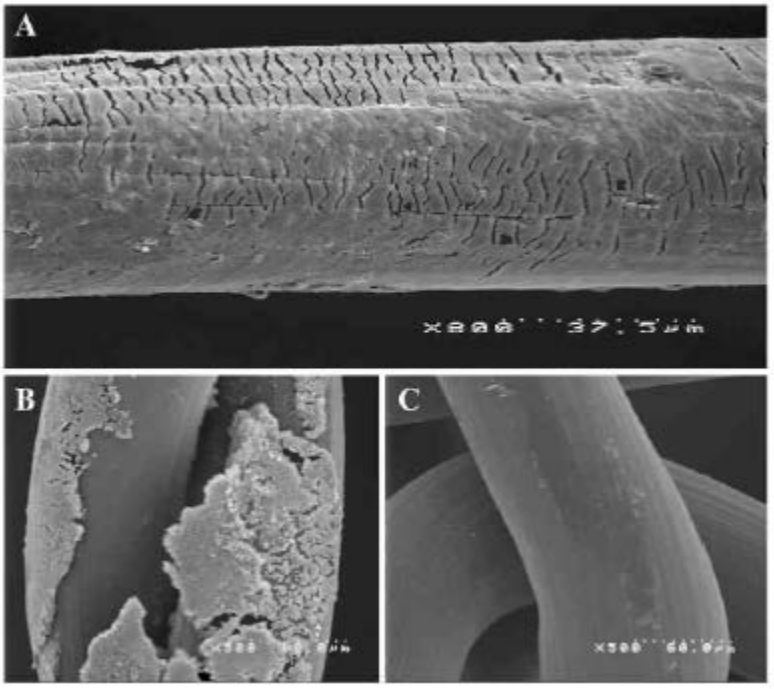


Fig. 1 from de Tayrac R and Letouzey V, Basic science and clinical aspects of mesh infection in pelvic floor reconstructive surgery. Int Urogynecol J 2011 Jul;22(7):775-80.

Similarly, Ong and colleagues published an abstract in 2016 that looked at in vivo degradation of polypropylene meshes. They used both blue and clear Prolene fibers and noted that they produced the same color of flakes following explantation, indicating that the Prolene had not oxidized, or else the flakes coming off the blue fibers would have been blue and the flakes coming off the clear fibers would have been clear. Rather, they were identical translucent or sometimes clear flaking material. And as noted by de Tayrac and Letouzey, progressive cleaning removed “bulk tissue and regions with cracked material on the explant surfaces, exposing clean, smooth,

unoxidized and non-degraded fibers . . . ." The authors concluded that "Explanted Prolene meshes did not undergo meaningful or harmful degradation in vivo. Instead, the cracked layer was composed of adsorbed protein coating arising from a well-established phenomenon occurring immediately upon implantation in vivo." (Ong KL, et al., The Myth: In Vivo Degradation of Polypropylene Meshes. Int Urogynecol J 2016;27 (Suppl 1):S19-S149, S37, PP19.) These studies indicating a lack of degradation are most consistent with my clinical experience using these meshes, and most consistent with the previously discussed body of literature reporting the safety and efficacy of the slings.

v. Roping, Curling, Fraying, and Particle Loss

If the TVT and TVT-O meshes are implanted according to the IFU and Ethicon's training materials, roping, curling, and fraying, is not an issue. The peer-reviewed published medical literature regarding the slings does not discuss these issues, and I have not seen any clinically significant roping, curling, or fraying in my practice. I have not observed particle loss to be an issue, either. In the event that particle loss were to occur, however, it would not be a concern, as it is the same safe, biocompatible Prolene that has been used in sutures for many decades, and that was approved as safe and effective by the FDA in April 1969. (Librojo Declaration at ¶ 9.)

vi. Excessive Stiffness of Laser-Cut Mesh

The TVT and TVT-O slings can be obtained with either a laser-cut or mechanically cut edges. I understand that plaintiffs' experts in this litigation have contended that laser-cut mesh is too stiff, which leads to pain and erosions. The literature does not support the existence of a clinically significant difference between laser-cut and mechanical-cut meshes. The literature published prior to 2007 when laser-cut mesh first became widely available reports very favorable safety and efficacy, and the literature published after 2007 reports the same safety and efficacy. Based on my discussions with urogynecologist colleagues, this is not a distinction that practicing surgeons care about. My experience with both the laser-cut and mechanically-cut slings has been very positive. I have seen no clinically significant differences in success or safety when using either of these products.

vii. Weight and Pore Size

It has also been contended by plaintiffs' experts in this litigation that the mesh in the TVT and TVT-O slings is heavyweight mesh and small pore mesh. As for the weight of the mesh, there is no agreed-upon classification for what constitutes heavyweight meshes. I have never observed the weight of the mesh to be problematic in my practice, nor does the literature report any such problems attributable to the weight of the mesh in the TVT and TVT-O slings.

The Prolene mesh used in the TVT and TVT-O slings is Type I (i.e., macroporous) mesh. The pores are so large that one can see through them. They are large enough to allow for good tissue ingrowth, and also to clear any bacteria that may

be present. Type I meshes, according to the Amid classification, are meshes that are "totally macroporous," with pore sizes "larger than 75 microns, which is the required size for admission of macrophages, fibroblasts (fibroplasia), blood vessels (angiogenesis) and collagen fibers into the pores." (Amid PK, Classification of biomaterials and their related complications in abdominal wall hernia surgery. Hernia 1997;1:15-21.) The pore size of the TVT and TVT-O mesh has been reported to be 1,379 microns, which is more than 17 times the size needed to be considered Type I, totally macroporous mesh, and has the largest pore size of any stress incontinence mesh devices. (Moalli P, et al., Tensile properties of five commonly used mid-urethral slings relative to the TVT. Int Urogynecol J 2008;19:655-63.) The 2015 Cochrane Review by Ford and colleagues also notes that "[m]acroporous meshes (pore size in excess of 75 µm) easily allow for macrophages, leukocytes, fibroblasts, blood vessels and collagen to transverse the pores: thus macroporous meshes promote tissue host ingrowth with resultant biocompatibility and low risk of infection (Amid 1997). Monofilament tapes are widely available and now predominate in current clinical practice." (Ford 2015.)

Larger-pore, lighter-weight meshes like Ultrapro have been developed, but did not prove to be feasible in Ethicon's testing. A transobturator sling made with Ultrapro mesh stuck to the sheaths during cadaver testing, (ETH.MESH.09922570.) Furthermore, a group of surgeons from Turkey investigated the use of Prolene Soft mesh, Ultrapro, and Vypro meshes and still observed complications such as vaginal erosion, urine retention, recurrent incontinence, and de novo urgency. (Okulu E, et al., Use of three types of synthetic mesh material in sling surgery: A prospective randomized clinical trial evaluating effectiveness and complications. Scand J Urol. 2013;47:217-24.) There is no mesh or biologic graft material that has been more studied than the TVT and TVT-O mesh, and none that has been shown to be safer, more biocompatible, or more effective in treating stress incontinence.

g. The Instructions for Use, Surgeon's Resource Monograph, and Brochures

Each TVT and TVT-O device is packaged with an Instructions for Use ("IFU") document. Each IFU describes the device, lists the procedural steps involved in implanting the device, and sets forth warnings and adverse reactions potentially associated with the device. The IFUs instruct the surgeon to "Please read all information carefully," and warn that "Failure to properly follow instructions may result in improper functioning of the device and lead to injury." (TVT IFU ETH.MESH.05222672-705; TVT-O IFU ETH.MESH.00860239-310.) The IFUs warn of the potential for blood vessel injury, nerve injury, bladder injury, bowel injury, bleeding, infection, urethra injury, extrusion, erosion, fistula formation, inflammation, de novo detrusor instability, and urinary tract obstruction. The TVT-O IFU further warns that transient leg pain lasting 24-48 hours may occur.

It must be noted, though, that pelvic floor surgeons who perform anti-incontinence surgeries know from their education, training, and experience that all anti-incontinence surgeries share the same basic set of risks, including bleeding, infection, pain, pain with intercourse, nerve damage, organ damage, failure of the procedure,

post-operative retention, and post-operative OAB. This list of risks is the same for both non-mesh surgeries such as the Burch procedure and autologous fascial sling surgeries and mesh surgeries like the TVT and TVT-O procedures. Furthermore, it is commonly known by urologists, gynecologists, and urogynecologists performing anti-incontinence surgeries that if any complication occurs in connection with a surgery, that complication could be temporary, or it could be a permanent complication. Likewise, it is commonly known among pelvic floor surgeons that any complications occurring in connection with any surgery could be mild and not bothersome to the patient, or they could be severe and extremely bothersome. (ACGME Program Requirements for Graduate Medical Education in Female Pelvic Medicine and Reconstructive Surgery Pt. IV.A.5.b).(3)(b); ABOG and ABU Guide to Learning in Female Pelvic Medicine and Reconstructive Surgery 2012, Pt. VI.C; AUGS Resident Learning Objectives.) IFUs, in my opinion, do not need to spell out this basic information for surgeons. The IFUs for the TVT and TVT-O devices, in my opinion, are appropriate and allow for the safe use of the devices by the intended users—pelvic floor surgeons. It is not necessary, in my opinion, for the IFU to warn of risks such as dyspareunia, chronic pain, recurrent incontinence, or the potential need for revision surgeries, as those are commonly known risks for pelvic floor surgeons. (21 CFR Pt. 801, Sec. 801.109 (device labeling does not need to include commonly known information regarding relevant hazards); FDA Device Labeling Guidance #G91-1 (noting that an adverse reaction as an undesirable effect reasonably associated with the use of the device).

Another helpful resource Ethicon made available regarding the TVT device was the Surgeon's Resource Monograph, which was a report prepared from a June 2000 meeting which had a panel of seventeen surgeons who had performed more than 1,200 TVT cases. It contained guidance on patient selection, procedural tips, and information regarding potential complications. (Surgeon's Resource Monograph.) I was introduced to the TVT-R by an Ethicon sponsored physician in Cincinnati, OH in 2000. I was introduced to the TVT-O by Dr. Tim McKinney at a cadaver course in Seattle, WA in 2004. My introductions to the devices included instructions on implanting the devices and a discussion of potential complications associated with the devices and the management of those complications.

I also found the brochures for the TVT family of products helpful, and gave them to my patients as one part of our discussion regarding the potential risks and benefits of the procedures. The brochures discuss the various types of urinary incontinence, the common causes of SUI, and the common symptoms of SUI. The brochures encouraged patients to talk to their surgeon about their problem, and suggested questions they could ask. It also suggested potential non-surgical treatments that the patient could explore, and it explained how the mid urethral slings work. The brochures also provided information regarding the risks of the procedure. All of this information was conveyed in easy-to-understand language. While the brochures are not a substitute for a comprehensive discussion of risks and benefits between my patients and me, they are helpful.

Based on the information discussed in this report, and on my experience using the devices to treat my patients' stress urinary incontinence, it is my opinion that the

benefits of the TVT and TVT-O devices far outweigh the risks associated with the devices. The design of the devices is safe and not defective.

Date: ____**1/31/17**_____

_____
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Columbus, OH 43210
M.D., 1981-1983

University of South Dakota, School of Medicine
Masters Degree of Science
2007 - 2011

RESIDENCY

Ohio State University, School of Medicine
Columbus, OH
Obstetrics and Gynecology Residency, 1983-1987

BOARD CERTIFICATION

American Board of Obstetrics and Gynecology, 1990
Rececrtified 2/28/2000 - 12/31/20010
Maintenance of Certification – initiated 2010 for 6 year certification

Female Pelvic Medicine and Reconstructive Surgery

Board Certified – 6 21 2013

MEDICAL LICENSURE

State of South Dakota (1930). July 1987

State of Iowa (26229). September 1988

MILITARY SERVICE

United States Navy
Defense Intelligence Agency
19[illegible]0-19[illegible]4

PROFESSIONAL AFFILIATIONS

Fellow. American College of Obstetricians and Gynecologists
1990-present

Fellow. American College of Surgeons
2009-present

Member. American Urogynecology Society
2002-present

Member. International Continence Society
2004-present

Member. International Urogynecology Association
2004-present

Member. South Dakota State Medical Association
198[illegible]-present

Member. Seventh District Medical Society
198[illegible]-present

Member. American Association of Gynecological Laparoscopists
1990-present

Member, American Institute of Ultrasound in Medicine
1987-present

Member. American Fertility Society
1994-present

Member, South Dakota Foundation for Medical Care

STAFF APPOINTMENTS

Active, Sanford Hospital
Sioux Falls, SD, 1987-present

Active, Avera McKennan Hospital
Sioux Falls, SD, 1989-present

Staff Privileges. Sioux Falls Surgical Center
Sioux Falls. SD. 1989-present

Courtesy. Merrill Pioneer Memorial Hospital
Rock Rapids. IA
1993-present

Courtesy. Northwest Iowa Health Center
Sheldon. IA
1993-present

FACULTY APPOINTMENTS

Clinical Professor. University of South Dakota School of Medicine
Sioux Falls. SD. 1988-present

PRACTICE EXPERIENCE

Sanford Clinic. OB-GYN. Ltd., 1987-2004
Sioux Falls. SD

Sanford Clinic. Female Pelvic Medicine & Reconstructive Surgery, 2004-present
Sioux Falls. SD

RESEARCH PROJECTS

Comparison of Umbilical Cord pH to Apgar Scores in Infants Delivered by Cesarean Section, 1985

Amniotic Fluid OD650 as Rapid Predictor of Fetal Lung Maturity, 1986

PGE2 as a Primary Agent for Induction of Labor in Term and Post-Term Infants, 198"

Differential gene expression in uterosacral ligament and full thickness anterior vaginal tissue from patients with recurrent and primary pelvic organ prolapse – presented at the International Urogynecology Association meeting in Lisbon, Portugal June 2011- submitted for publication 12/15/2011.

Phase II of American Indian Women incontinence Study "Therapy and Care delivery" – funding provided by National Institutes of Health Grant. Study ongoing.

PUBLICATIONS

Fiegen, M.M., Benson, K.D., et.al: Prevalence of urinary incontinence in American Indian Women. Int Urogynecol J 2012; 23(6): 473-479.

Fiegen, M.M.: Laparoscopic Assisted Vaginal Hysterectomy. Op. Tech. In GYN Surgery 1997; 2(3):144-153.

Watson, W.J., Fiegen, M.M.: Fetal Thyrotoxicosis Associated Nonimmune

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LECTURES

Back in Control: The Story of Urinary Incontinence – 2004

Urinary Incontinence: A Midlife Crisis – 2006

Incontinence: Are these really the Golden Years - 2007

Lower Urinary Tract concerns during Pregnancy and Postpartum – 2007

The Changing Face of Urinary Incontinence – 2007

Overactive Bladder: Evaluation and Therapy - 2008

Michael Fiegen

General Reliance List
in Addition to Materials Referenced in Report

MDL Wave 4

Michael Fiegen Materials List

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Ahn, C. Analysis of voiding dysfunction after transobturator tabe procedure for stress urinary incontinence. Korean J Urol 2015; 56: 823-830
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Albo M, Richter, Zimmern, Moalli, Sirls. - NEJM - SISTEr study - Burch Colposuspension versus Fascial Sling to Reduce Urinary Stress Incontinence. N Engl J Med 2007;356:2143-55.
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Alcalay, M. Burch colposuspension: a 10-20 year follow up. British Journal of Obstetrics & Gynaecology. 1995; 102: 740-745
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Amid PK. Biomaterials for abdominal wall hernia surgery and principles of their applications. Langenbecks Arch Chir (1994) 379:168-171
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Michael Fiegen Materials List

Medical Literature

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Medical Literature

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Bacterial Analysis of Explanted Transvaginal Meshes
Biocompatibility of Meshes
Chronology - D-9
DEPO.ETH.MESH.00000367-68 - T-2265 (Prolene Explants - IR Microscopy)
DEPO.ETH.MESH.00004755 - Report: Quebec Explants. 1.20.88
Deposition Subject Matter-Design and Development of Mesh Products
Device Labeling Guidance #G91-1
DX23600-R.1-3 - Prolene Resin Manufacturing Specifications 1.23.03
Email string re - Revised write up of the DeLeval and Waltregny visit
ETH MESH 05795421-508 - Gynecare TVT Tension-Free Support for Incontinence: Professional Education Slides.
ETH MESH 08476210-6342 - TVT 510(k)
ETH.MESH.00006636 - Interim report mesh explants pelvic floor repair
ETH.MESH.00006796 - Presentation-Stand and Deliver-Pelvic Floor Repair
ETH.MESH.00030098 - Memo from Anthony Powell and Marianne Kaminski to Gynecare Continence Health Sales Team re GYNECARE TVT Physician Training Policy
ETH.MESH.00071794 - Email re: TVT IFUs on tape extrusion, exposure and erosion
ETH.MESH.00074499 - Gynecare Prolift +M-Training Presentation
ETH.MESH.00130934-41 - July 30, 1998 Meeting Notes re TVT
ETH.MESH.00161131-32 - TVT-Innovative Surgical Alternative for the Treatment of Female SUI
ETH.MESH.00167104-110 - 2006 Apr 19 - Laser Cut Mesh for Gynecare TVT- CER Laser Cut Mesh
ETH.MESH.00211259-60 - Email string re - TVT Exact IFU
ETH.MESH.00220335-36 - 12.2.1999 Memo re: Biocompatibility Risk Assessment for Soft Prolene Mesh.
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ETH.MESH.01238454-56 - Email string re-TVTO length
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ETH.MESH.01808311-318 - Trip Report Michael Tracey
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ETH.MESH.01813975-78 - Email string re-FDA Prep-Plaintiff's Exhibit 460
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ETH.MESH.01822361-62 - Dan Smith Email regarding TVT-Secur leading to less retention
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ETH.MESH.02026591-95 - MSDS-c4001 Polypropylene Homopolymer
ETH.MESH.02090196-209 - Plaintiff's Exhibit 4085-04.15.2008
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ETH.MESH.02211890 - Bates stamped non-color version - LNE Pore Size Testing of TVT
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ETH.MESH.02234874-910 - Waltregny Presentation- A modified version of GYNECARE TVT™ Obturator System Tension-free Support for Incontinence with a shorter tape and reduced dissection
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ETH.MESH.03915380 - Axel Arnaud email re Dr. Lucente-TVT Procedure Improvements-Prevention of Overstretching
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ETH.MESH.03932912 - The History of TVT
ETH.MESH.03941623 - DeLeval Email RE: TVT ABBREVO ALERT - French and English Email and English Translation Certification Plaintiff's Exhibit 3619- Perry
ETH.MESH.04044797-800 - TVT Update Jacquetin, B - Klute, C - Stanton, S - Ulmsten, U - Success and Complications
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ETH.MESH.06927231-235 - Email string re-Scion PA commercail recommendation
ETH.MESH.07192929 - Investigating Mesh Erosion in Pelvic Floor Repair Powerpoint
ETH.MESH.07226481 - Ethicon (Burkley) response to Clave paper re degradation
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ETH.MESH.07318311-313 - de Leval Email Re: TVT ABBREVO ALERT - French and English Email and English Translation Certification - Plaintiff's Exhibit 3613
ETH.MESH.07383730-31 - Email string re-Ultrapro mesh information-identical mesh to Prolift +M
ETH.MESH.07387254-257 - Email RE: August Status Report - Gynecare marketing [11.6.13 Exhibit T-3365]

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ETH.MESH.09747038-097 - Medscand Agreement
ETH.MESH.09747337-369 - Asset Purchase Agreement
ETH.MESH.09888187-223 - Seven Year Data for Ten Year Prolene Study - Plaintiff's Exhibit 4102
ETH.MESH.09922570 - MO PA (TOPA) R&D Memo on PA Mesh Assessments for MO-PA
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P4118 - Figure 26: J8041-13675 (Photograph)
P4122 - SEM Figure 183: Sample J7959 13409 (Photographs)
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Deponent [Date of Deposition]
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Angelini, Laura - 09.17.2013 Deposition Testimony
Angelini, Laura - 11.06.2013 Deposition Testimony
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Rovner, Eric - 08.26.2014 Deposition Testimony
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Smith, Dan - 08.21.2013 Deposition Testimony
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Elliott, Daniel (TVT-O General) 3.6.16
Elliott, Daniel (TVT General) - 9.26.2015
Margolis, Michael (Batiste TVT-O) - 11.26.2013
Margolis, Michael (Lewis TVT) - 11.25.2013
Margolis, Michael (Beltz Prolift, TVT-O) - 9.10.2016
Margolis, Michael (Carlino TVT) - 11.21.2015
Margolis, Michael (Ramirez TVT-O) - 3.12.2016
Rosenzweig, Bruce (Carlino TVT) - 1.13.2016
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Document Description [Bates Range]
2003 (14 Day Rabbit Study) PSE 02-0579 Stamped Copy March 10, 2003 R&D - Central File: ETH-11280; ETH-11285-297; ETH-11312-315
2006 Mar 3 Flatow memo - CPC-2006-0165 Performance evaluation of TVT PROLENE blue Mesh_ Elongation Properties of Mechanical Cut verses Laser Cut
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Bacterial Analysis of Explanted Transvaginal Meshes
Biocompatibility of Meshes
Chronology - D-9
DEPO.ETH.MESH.00000367-68 - T-2265 (Prolene Explants - IR Microscopy)
DEPO.ETH.MESH.00004755 - Report: Quebec Explants. 1.20.88
Deposition Subject Matter-Design and Development of Mesh Products
Device Labeling Guidance #G91-1
DX23600-R.1-3 - Prolene Resin Manufacturing Specifications 1.23.03
Email string re - Revised write up of the DeLeval and Waltregny visit
ETH MESH 05795421-508 - Gynecare TVT Tension-Free Support for Incontinence: Professional Education Slides.
ETH MESH 08476210-6342 - TVT 510(k)
ETH.MESH.00006636 - Interim report mesh explants pelvic floor repair
ETH.MESH.00006796 - Presentation-Stand and Deliver-Pelvic Floor Repair
ETH.MESH.00030098 - Memo from Anthony Powell and Marianne Kaminski to Gynecare Continence Health Sales Team re GYNECARE TVT Physician Training Policy
ETH.MESH.00071794 - Email re: TVT IFUs on tape extrusion, exposure and erosion
ETH.MESH.00074499 - Gynecare Prolift +M-Training Presentation
ETH.MESH.00130934-41 - July 30, 1998 Meeting Notes re TVT
ETH.MESH.00161131-32 - TVT-Innovative Surgical Alternative for the Treatment of Female SUI
ETH.MESH.00167104-110 - 2006 Apr 19 - Laser Cut Mesh for Gynecare TVT- CER Laser Cut Mesh
ETH.MESH.00211259-60 - Email string re - TVT Exact IFU
ETH.MESH.00220335-36 - 12.2.1999 Memo re: Biocompatibility Risk Assessment for Soft Prolene Mesh.
ETH.MESH.00259473-503 - Exhibit T-254
ETH.MESH.00260591-592 - Dan Smith Email Plaintiff's Exhibit 180
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ETH.MESH.00526473-74 - Allison Brown Email re-Laser-cut Mesh
ETH.MESH.00541379-80 - Memo to File RE: Mesh Draying for TVT Devices 11.18.03
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ETH.MESH.00687819-22 - Email string re-Laser cut mesh
ETH.MESH.00836558-59 - Email string re - TVT-O groin pain
ETH.MESH.00857821 - Top Ten Reason to pursue Gynecare TVT Obturator System
ETH.MESH.00858080-081 - Perry Trial - Plaintiff's Exhibit 2313
ETH.MESH.00858094-95 - Gynecare R&D Monthly Update - March
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ETH.MESH.00858175-176 - Mulberry Weekly Meeting MINUTES for 6.3.03
ETH.MESH.00858252-53 - 2004 Memo from London Brown to Dan Smith re Mechanical Cut vs. Laser Cut Mesh Rationale
ETH.MESH.00860142-144 - Email string re-Sample Media TVTO
ETH.MESH.00862176-185 - Prolene Revision History for MS-729-001
ETH.MESH.00862754-757 -6.9.03 Dan Smith Email Re: Double Edged Sword
ETH.MESH.00863391 - T-366 - Dan Smith email - particle loss
ETH.MESH.00870466 - Ethicon Expert Meeting-Meshes for Pelvic floor
ETH.MESH.00918015 - Sunoco MSDS 04.13.05
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ETH.MESH.01202189 - Stale Kvitle Email regarding Mini Me follow up from our visit May 20, 2009
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ETH.MESH.01785259-260 - Email string re: +M relaxation
ETH.MESH.01808311-318 - Trip Report Michael Tracey
ETH.MESH.01809082-83 - Memo re-VOC on new laser cut TVT mesh
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ETH.MESH.02017152-56 - 02.23.2007 Ethicon Expert Meeting: Meshes for Pelvic Floor Repair
ETH.MESH.02026591-95 - MSDS-c4001 Polypropylene Homopolymer
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ETH.MESH.02211890 - Bates stamped non-color version - LNE Pore Size Testing of TVT
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ETH.MESH.02622276-79 - Issue Report; TVT Retropubic 2001.
ETH.MESH.02654027-028 - TVT-O Issue Report 2006
ETH.MESH.03259439-40 - 4.24.2009 Gauld email chain re Green Journal
ETH.MESH.03427878-883 - TVT IFU - (11.29.10 to11.26.14)
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ETH.MESH.03715978-79 - Weisberg email re - TVT Question
ETH.MESH.03751819 - The Science of "What's Left Behind"…Evidence & Follow-Up of Mesh Use for SUI.
ETH.MESH.03905472-77 - Email string re-TVT recommendation from Dr. Alex Wang
ETH.MESH.03906976 - Exhibit 2227 - TVOT-04.30.2003-Meeting Report
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ETH.MESH.03910418-21 - Email string re-Mini TVT - mesh adjustment
ETH.MESH.03911107-08 - Email string re-TVT complications (an Prof. Hausler)
ETH.MESH.03913357-359 - Axel Arnaud Email 5.31.07 Re TVT TVT-O
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ETH.MESH.03932909-911 - Confidential - History of TVT-O
ETH.MESH.03932912 - The History of TVT
ETH.MESH.03941623 - DeLeval Email RE: TVT ABBREVO ALERT - French and English Email and English Translation Certification Plaintiff's Exhibit 3619- Perry
ETH.MESH.04044797-800 - TVT Update Jacquetin, B - Klute, C - Stanton, S - Ulmsten, U - Success and Complications
ETH.MESH.04048515-520 - Carl Nilsson KOL Interview Project Scion 06.18.08
ETH.MESH.04050265-267 - Hinoul Letter regarding De Leval Meeting - Pain in Adductor in young Active Patients
ETH.MESH.04079609 - Gynecare TVT Abbrevo Professional Education (Dr. Babcock).
ETH.MESH.04081189-90 - Meeting Agenda
ETH.MESH.04081301-02 - Memo re - Items need attention
ETH.MESH.04082973-74 - Possible Complications for Surgeries to Correct POP and SUI
ETH.MESH.04092868-69 - Email re : 10100080654 and TVT IFUs
ETH.MESH.04094863-64 - 01.29.2009 email from Bryan Lisa to Meng Chen
ETH.MESH.04097335-36 - Meng Chen - Medical Assessment-Tracking 10100054041 for mesh fraying
ETH.MESH.04381806-19 - 1997 Literature Review on Biocompatibility of Prolene Sutures and Implants
ETH.MESH.04384112 - Biocompatibility Risk Assessment for the TVT-L Device - June 6, 2001
ETH.MESH.04938298-299 - Piet Hinoul Email Re: Prof. de Leval - TVT Abbrevo
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ETH.MESH.05217098-100 - Modified Prolene Mesh Clearance Letter
ETH.MESH.05217103-144 - Modified Prolene Mesh 510(k)
ETH.MESH.05225380-384 - TVT IFU - (09.08.00 to 11.26.03)
ETH.MESH.05315240-65 - 28 Day Rat Study
ETH.MESH.05316775-812 - Report, PSE Accession NO. 02-0579-T-2133
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ETH.MESH.05347751-762 - Email string re Investigator-initiated studied policy
ETH.MESH.05479411 - The (clinical) argument of lightweight mesh in abdominal surgery
ETH.MESH.05479535
ETH.MESH.05529274-75 - Gynecare TVT Tension Free Support for Incontinence
ETH.MESH.05529653 - Email string re - Problem statements for TVT brainstorming meeting
ETH.MESH.05572912-913 - Ethicon Professional Education Description
ETH.MESH.05588123-126 - Stephen Wohlert Email - AW: How inert is polypropylene? July 9, 2007
ETH.MESH.05644163-171 - Pelvic Floor Repair-Surgeon's Feed-back on Mesh Concept
ETH.MESH.05795537-99 - TVT Professional Education Program: Speaker's Guide.
ETH.MESH.05799233-39 - TVT Exact IFU
ETH.MESH.05916450 - Chronic Pain-Prevention, Future - Bioengineers point of view-D21929 (Powerpoint)
ETH.MESH.05918776 - Email re: Marlex Experience
ETH.MESH.05958248 - Surgeons Resource Monograph
ETH.MESH.05998835-836 - Piet Hinoul Email Re: ALERTE TVT ABBREVO
ETH.MESH.06592243 - 09.14.2012 Email from Carl Nilsson to Laura Angelini
ETH.MESH.06695438 - Justification for Utilizing the Elasticity Test as the Elongation Requirements on TVT LCM
ETH.MESH.06881576-80 - Email string re-TVTO
ETH.MESH.06887138-40 - Waltregny email re IFU written on behalf of Professor de Leval.
ETH.MESH.06887241-244 - David Waltregny email 7.16.04 re TVT-O
ETH.MESH.06887244 - 07.16.04 David Waltregny email to Dan Smith re: TVT-O.
ETH.MESH.06887245-246 - Dan Smith Email 7.15.04
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